

K081960

Align Technology, Inc.,
Modified Invisalign® system

DEC 17 2008

510(k) Premarket Notification Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92 and SMDA 1990.

The assigned 510(k) number is _____.

1. Manufacturer's Information:

- | | |
|---------------------|---|
| a. Company Name: | Align Technology, Inc. |
| b. Company Address: | 881 Martin Ave.,
Santa Clara, CA 95050 |
| c. Company Phone: | (408) 470-1244 |
| d. Company Fax: | (408) 470-1011 |
| e. Contact Person: | Sangeeta Sachdeva
Manager,
Regulatory Affairs
Align Technology, Inc. |

2. Prepared on: June 26th, 2008

3. Device Identification:

- | | |
|--------------------------------------|--|
| a. Current Trade (proprietary) Name: | Invisalign system |
| b. Generic Name: | Invisalign, Aligners |
| c. Classification Name: | Orthodontic Plastic
Brackets (Sequential
Aligners) |
| d. Classification regulation | 21CFR 872.5470 |
| e. Product Code | NXC |
| f. Device class: | II |
| g. Advisory panel | Dental |

4. Predicate Device Identification:

- a. Current Trade (proprietary) Name: Invisalign system
- b. Generic Name: Invisalign, Aligners
- c. Classification Name: Orthodontic Plastic Brackets - 21CFR 872.5470 (Sequential Aligners)
- d. Product Code NXC
- e. Device class: II

5. Indications for Use:

The Invisalign system is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

6. Device Description:

The current Invisalign system is a series of clear plastic aligners that are used to replace traditional orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth. This series of aligners moves the teeth gently, and in small increments, from their original to their final treated position for improved dental alignment.

This 510(k) Premarket Notification is being submitted because Align Technology, Inc. is making labeling changes that affect the indications for use, contra-indications, and precautions of the currently-commercialized Invisalign system. The technological characteristics of the modified and currently-marketed predicate device, such as design, raw material, and chemical composition, and their manufacturing processes and related software, are identical.

The labeling modifications include:

- I. Expansion of the indications of use to permit treatment of patients who present with malocclusion without the limitation of permanent dentition.
- II. Removal of certain contra-indications that excluded patients with certain complex malocclusions from getting treated with the Invisalign system. These patients may or may not need additional orthodontic procedures to achieve the desired treatment outcome, and this is captured in the added precautions.

III. Addition of precautions corresponding to the removal of contraindications.

Thus, the modified Invisalign system with the proposed labeling changes will allow the treatment of patients with malocclusion, including, but not limited to, those with primary dentition present (including mixed dentition), as well as of patients with severe open bite, severe overjet, skeletally narrow jaw, dental prostheses/implants, and/or those who require surgical correction.

7. Software:

There are no changes in the software compared to the existing Invisalign system. The software design and development, software development methodology, software development process and environment are identical for the existing predicate device and the modified Invisalign system.

8. Technological Characteristics:

A comparison of the current and proposed Invisalign system demonstrates that the devices are equivalent in terms of technology, material-based physical and performance characteristics.

9. Substantial Equivalence Information:

This Premarket Notification is being submitted solely to incorporate the above listed labeling changes to the existing Invisalign system (K981095).

- There are no changes in the technological characteristics of the modified device when compared to the predicate device. The design, raw material, and chemical composition, device features as well as technical characteristics of the modified device and existing predicate device are identical.
- There are no changes in the manufacturing processes and related software required to accommodate the labeling changes.

Thus, based on the similar indications for use and same technological, material, and performance characteristics of the currently marketed, predicate device (K981095) and the Invisalign system with the modified labeling, the two are considered substantially equivalent (21 CFR 807.100).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sangeeta Sachdeva
Manager, Regulatory Affairs
Align Technology, Incorporated
881 Martin Avenue
Santa Clara, California 95050

DEC 17 2008

Re: K081960
Trade/Device Name: Invisalign® System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: December 10, 2008
Received: December 12, 2008

Dear Ms. Sachdeva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Align Technology, Inc.
Modified Invisalign® system
510(k) Premarket Notification
Company Confidential

K081960

Align Technology, Inc.,
Modified Invisalign® system

Indications for Use

510(k) Number if Known: To be assigned by FDA
Device Name: Invisalign® system
Indications of Use: The Invisalign® system is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Please do not write below this line.

Concurrent of CDRH, Office of Device Evaluation (ODE)

Susan Russo
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081960

Prescription Use: X
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use: _____
(Part 21 CFR 801 Subpart C)